

ABSTRACT

An extended release acetaminophen composition comprises a plurality of discrete particles containing acetaminophen which, when contained within a gelatin capsule and assayed in a USP Apparatus I rotating basket at 50 rpm in 900 mL of phosphate buffer at pH 5.8 and 37°C, exhibits about 40 percent to about 53 percent acetaminophen dissolution at one-half hour, about 50 percent to about 68 percent dissolution at 45 minutes, about 57 percent to about 77 percent acetaminophen dissolution at one hour, and about 82 percent to about 92 percent acetaminophen dissolution at two hours. After six hours, the contemplated extended release acetaminophen composition exhibits substantially complete dissolution. A process for treating a human patient with the extended release acetaminophen composition is also disclosed.